AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes changes to Figures 1-16. These sheets, which include Figures 1-16, replace the original sheets including Figures 1-16. As requested by the examiner, a set of formal drawings is submitted herein.

Attachment: Replacement Sheets.

REMARKS

Claims 161-166, 261-262, 264-267, 269, and 271-279, as amended, appear in this application for the Examiner's review and consideration. Claims 263, 268, and 270 have been canceled without prejudice. Applicants fully reserve their rights to prosecute the subject matter of any cancelled claim in one or more continuation, continuation-in-part, or divisional applications. Claims 161-162, 264-267, 269, 271-273, and 275 have been amended to more particularly point out the claimed subject matter, to correct inadvertent minor spelling and editorial errors, and to correct antecedent basis within the claims. Thus, no new matter has been added. Therefore, entry of these amendments is respectfully requested.

Applicants' appreciate the courtesies extended to their representative, Craig L. Puckett, Reg. No. 43,023, during the interview with Examiner Evelyn Huang conducted on August 20, 2004. The substance of the interview and the reasons presented at the interview as warranting favorable action are included in the comments below.

Claims 161-166 and 263-279 stand rejected under 35 U.S.C. § 112, first paragraph as allegedly failing to comply with the written description requirement for the reasons set forth on pages 2 and 3 of the Office Action. Applicants respectfully traverse.

As long as a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if not every nuance of the claims is explicitly described in the specification, then the adequate written description requirement is met. *In re Alton*, 76 F.3d 1168, 37 U.S.P.Q.2d 1578 (Fed. Cir. 1996). "*Ipsis verbis* disclosure is not necessary to satisfy the written description requirement of section 112." *Fujikawa v. Wattanasin*, 93 F.3d 1559, 39 U.S.P.Q.2d 1895 (Fed. Cir. 1996).

The statements made in the Office Action to reject the claims, demonstrates that each claim was described sufficiently in the specification to meet applicant's burden under § 112, first paragraph. The Office Action rejected claims 161-166 and 263-279 stating in part, that "... the above general statements in the specification is for the generic zolpidem hemitartrate, but is irrelevant to the specific forms of zolpidem hemitartrate, such as form D, which is characterized by certain X-ray diffraction patterns. The specification only discloses a zolpidem hemitartrate *form D having the X-ray powder diffraction pattern having peaks at 7.1, 9.5, 14.1, 19.6 and 24.5 plus or minus 0.2 degrees two-theta*, which is a monohydrate or hemiethanolate (page 18 of the specification)." (emphasis in original).

Although applicants disagree that the specification **only** discloses zolpidem hemitartrate form D, as other polymorphs are disclosed, applicants submit that the examiner's

own statements show that the claims are described in sufficient detail to meet § 112, first paragraph. The Office Action also quotes the specification "(page 18 of the specification)" to support its argument, thus, further supporting that the claimed subject matter is described in the specification.

To meet the description requirement applicants must describe the claimed subject matter in a manner sufficient for one of ordinary skill in the art to understand. As understood by applicants, the Office Action applies an incorrect standard to the description requirement. In order to meet the description requirement, the Office Action requires the applicants to describe each and every possible transformation that the polymorph of the claims may undergo, regardless how remote the possibility of such transformation. The legal standard, however, does not require the specification to describe any change to the recited polymorph or even speculate as to any possible change without regard to the remoteness of such change, but to described the claimed subject matter, *i.e.* zolpidem hemitartrate polymorph Form D.

The heightened burden for the description requirement, as applied in the Final Office Action, cannot be met by any application. An application written to meet each and every variation, transformation, or alteration regardless of possibility would be overly speculative and not based on the invention by the applicant. Thus, the newly applied standard, as understood by the applicants, cannot be met by any application because applicants would have to speculate as to possible changes by the polymorphs with complete disregard as to the recited subject matter or to the knowledge of one skilled in the art.

Moreover, as understood by the applicants, the rejection appears to be directed to the recitation of "hydrate" and "ethanolate." Claims 161-166, which do not contain such a recitation, should have been allowed for the same reasons as claims 261 and 262.

As claims 263 and 268 were cancelled, the § 112, first paragraph, rejection is moot. Accordingly, the zolpidem hemitartrate monohydrate and the zolpidem hemitartrate hemiethanolate are species of the disclosed zolpidem hemitartrate and thus, described in the specification to the extent necessary to meet the burden under § 112, first paragraph. Thus, the rejection of claims 161-166 and 264-267, 269, and 271-279 under 35 U.S.C. § 112, first paragraph, cannot stand and should be withdrawn.

Claims 165 and 273-278 stand rejected under 35 U.S.C. § 102(b) as anticipated by U.S. patent No. 5,891,891 to E. Benincasa ("the '891 patent") for the reasons set forth at page 2 of the Office Action. Applicants respectfully traverse.

It is axiomatic that for prior art to anticipate under § 102 it has to meet every element of the claimed invention. *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367,

1379, 231 U.S.P.Q. 81, 90 (Fed. Cir. 1986), *cert denied*, 480 U.S. 947 (1987). Although the use of additional references to confirm the contents of an allegedly anticipating reference is permitted, anticipation does not permit an additional reference to supply a missing claim limitation. *Teleflex, Inc. v. Ficosa North American Corp.*, 299 F.3d 1313 (Fed. Cir. 2002).

Under the doctrine of inherency, if an element is not expressly disclosed in a prior art reference, the reference will be deemed to anticipate a subsequent claim if the missing element "is necessarily present in the thing described in the reference, and that is would be so recognized by persons of ordinary skill." *Cont'l Can Co. v. Monsanto Co.*, 948 F.2d 1264, 1268, 20 U.S.P.Q.2d 1746, 1749 (Fed. Cir. 1991). "Inherent anticipation requires that the missing descriptive material is necessarily present, not merely probably or possibly present, in the prior art." *Trintec Indus., Inc. v. Top-U.S.A. Corp.*, 295 F.3d 1292, 1295, 63 U.S.P.Q.2d 1597 (Fed. Cir. 2002).

An anticipatory reference must disclose each and every element of claims 165 and 273-278. Claim 165 is dependent from claim 161 which recites a zolpidem hemitartrate Form D characterized by an X-ray diffraction pattern having peaks at about 7.1, 9.5, 14.1, 19.6, and 24.5 ± 0.2 degrees two-theta. Claim 165 further recites a pharmaceutical composition comprising the 161 zolpidem hemitartrate Form D, wherein the zolpidem hemitartrate is in the form of particles and a pharmaceutically acceptable carrier. The '891 patent does not disclose a zolpidem hemitartrate Form D, does not disclose any X-ray diffraction pattern, and does not disclose a pharmaceutical composition of zolpidem hemitartrate Form D. Therefore, the '891 patent fails to anticipate claims 165 and 273-278 because the reference fails to disclose each and every element recited in the claims.

If the rejection of the Office Action is under the doctrine of inherency, then the Office Action has the burden of putting forth each and every element that is not expressly disclosed in the '891 patent. However, the Office Action does not put forth any rationale or evidence tending to show inherency to support the argument of anticipation. The mere fact that a thing may result from a given set of circumstances is not enough. The Office Action must put forth a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic, *i.e.* zolpidem hemitartrate Form D, necessarily flows from the '891 patent. This burden is not met and therefor, the '891 patent fails to anticipate claims 165 and 273-278.

Claim 165 is dependent on claim 161, which recites a zolpidem hemitartrate Form D characterized by a particular X-ray diffraction pattern, a fact ignored by the Office Action. The Office Action generally equates the '891 patent pharmaceutical composition with the

composition of claim 165. This generalization, however, is in error because the generalization equates a non-crystalline compound with the crystalline zolpidem hemitartrate particle recited in claim 165. As a dependent claim the pharmaceutical composition of claim 165 has particles which comprise zolpidem having the crystal structure of claim 161. The Office Action mischaracterizes the claim 165 composition by ignoring the dependency of the claim upon clam 161 and the recitations as to the zolpidem hemitartrate Form D.

In an effort to reach the recited subject matter, the Office Action equates the term "particle" with "instant liquid composition." Although the zolpidem hemitartrate Form D may be present as a particle in a liquid suspension or in a solid dosage form, nevertheless, zolpidem hemitartrate is still zolpidem hemitartrate Form D with a particular X-ray diffraction pattern. Any other reading ignores the claim language. In this case, the claim reading by the Office Action completely ignores the term "particle," its ordinary meaning in the art, and the dependency upon claim 161. These errors are fatal to any anticipation argument grounded in the '891 patent.

An anticipatory reference must enable one of ordinary skill in the art as to the claimed subject matter. As disclosed in the present invention, zolpidem hemitartrate may crystallize as one of several polymorphs. Claim 161 recites a polymorph of zolpidem hemitartrate Form D, and claim 165 is dependent thereon. The general statement of the '891 patent fails to enable the skilled artisan to make the specific polymorph of the claim. In fact, the '891 patent provides a general description without any specific crystallization instructions. Therefore, as the '891 patent does not enable one of ordinary skill in the art to obtain any particular zolpidem hemitartrate crystal, much less the zolpidem hemitartrate Form D polymorph of claim 161 or 165, the '891 patent does not anticipate the present claims.

Accordingly, for the reasons discussed above, the rejection of claims 165 and 273-278 under 35 U.S.C. § 102(b) as anticipated by the '891 patent cannot stand and should be withdrawn.

Accordingly, it is believed that claims 161-166, 261-262, 264-267, 269, and 271-279 are now in condition for allowance, early notice of which would be appreciated.

If any outstanding issues remain, the examiner is invited to telephone the undersigned at the telephone number indicated below to discuss the same. No fee is believed to be due for the submission of this response. Should any fees be required, please charge such fees to Kenyon & Kenyon, LLP Deposit Account No. 11-0600.

Respectfully submitted,

Dated: 9/14/04

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